

LOW DOSE ASPIRIN- aspirin tablet, chewable
Pharbest Pharmaceuticals, Inc.

Drug Facts

Active Ingredient (in each tablet)

Aspirin 81mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Uses

- for the temporary relief of minor aches and pains or as recommended by your doctor
- ask your doctor about other uses for Chewable Aspirin 81 mg

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding.

The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer

- this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor

Ask a doctor before use if

- the stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you have asthma
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

taking a prescription drug for

- gout
- diabetes
- arthritis

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding: • feel faint • vomit blood • have bloody or black stools • have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms occur
- ringing in the ears or loss of hearing occurs

These could be signs of a serious condition

If pregnant or breast-feeding,

ask a health professional before use. **It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.**

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (800-222-1222).

Directions

- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: consult a doctor

Other information

- **Tamper Evident: Do not use if safety seal under cap is broken or missing**

- store at room temperature 20°-25°C (68°-77°F), excursions permitted between 15-30°C(59-86°F)

Inactive ingredients

Corn starch, dextrose monohydrate, FD&C yellow #6, orange flavor, silicon dioxide, sodium saccharine, stearic acid

Questions or comments?

call 866-562-2756 Mon-Fri 8 AM to 4 PM EST

PHARBEST

NDC 16103-366-11

Manufactured in the USA

Aspirin Regimen

Chewable

Aspirin

Low Dose

81mg Pain Reliever (NSAID)

***Compare to the active ingredient in BAYER® Chewable Aspirin**

Orange Flavored

1000 TABLETS

Talk to your doctor or other healthcare provider before using this product for your heart.

PHARBEST
NDC 16103-366-11

ASPIRIN REGIMEN

Chewable Aspirin
Low Dose

81mg Pain Reliever (NSAID)

**Compare to the active ingredient in BAYER® Chewable Aspirin*

Orange Flavored

1000 TABLETS

Talk to your doctor or other healthcare provider before using this product for your heart.

Manufactured in the USA

THIS PACKAGE FOR HOUSEHOLD WITHOUT YOUNG CHILDREN
TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Drug Facts
<p>Active ingredient (in each tablet) Aspirin 81 mg (NSAID) Pain reliever Nonsteroidal anti-inflammatory drug</p> <p>Uses</p> <ul style="list-style-type: none"> ■ for the temporary relief of minor aches and pains or as recommended by your doctor ■ ask your doctor about other uses for Chewable Aspirin 81 mg <p>Warnings</p> <p>Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, it changes the way the liver works. In some cases, these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.</p> <p>Allergy alert: Aspirin may cause a severe allergic reaction which may include: hives, facial swelling, asthma (wheezing), shock</p> <p>Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach ulcers or bleeding problems. ■ Take a blood thinner (anticoagulant) or steroid drug ■ Take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others) ■ Have 3 or more alcoholic drinks every day while using this product ■ Take more or for a longer time than directed</p> <p>Do not use ■ if you are allergic to aspirin or any other pain reliever/fever reducer ■ this product for at least 7 days after tonsillectomy or oral surgery unless directed by a doctor</p> <p>Ask a doctor before use if ■ stomach bleeding warning applies to you ■ you have a history of stomach problems such as heartburn ■ you have high blood pressure, heart disease, liver cirrhosis or kidney disease ■ you have asthma ■ you are taking a diuretic ■ diabetes ■ arthritis</p> <p>Ask a doctor or pharmacist before use if you are taking a prescription drug for ■ gout ■ stop use and ask a doctor if ■ an allergic reaction occurs. Seek medical help right away ■ you experience any of the following signs or stomach bleeding: ■ feel faint ■ heartburn ■ indigestion ■ have stomach pain ■ have skin rash ■ have swollen legs ■ get hives ■ pain, dizziness or lightheadedness ■ have a fever, rash, hives, or swelling that lasts more than 3 days ■ redness or swelling is present ■ ringing in the ears or loss of hearing ■ occurs ■ any new symptoms occur</p> <p><small>These could be signs of a serious condition</small></p> <p>If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Stop use at the first sign of heartburn, indigestion, or medical help or contact a Poison Control Center right away (800-222-1222).</p>
<p>Directions</p> <ul style="list-style-type: none"> ■ Drink 2 full glasses of water with each dose ■ adults and children 12 years and over Take 4 to 8 tablets every 4 hours not exceed 48 tablets in 24 hours unless directed by a doctor ■ children under 12 years Consult a doctor
<p>Other information</p> <ul style="list-style-type: none"> ■ Store at room temperature 20°-25°C (68°-77°F), excursions permitted between 15°-30° (59°-86°F).
<p>Keep this and all Bayer products out of the reach of children. See important information about Bayer products on the back of this package.</p> <p>Keep this and all Bayer products out of the reach of children. See important information about Bayer products on the back of this package.</p>

PHARBEST 16103-366-11

Manufactured by:
Pharbest Pharmaceuticals, Inc.
Farmingdale, NY 11735

LF#ev. 06/25

LOW DOSE ASPIRIN

aspirin tablet, chewable

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:16103-366
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	orange	Score	no score
Shape	ROUND	Size	8mm
Flavor	ORANGE	Imprint Code	PH034
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16103-366-05	1 in 1 CARTON	08/22/2007	
1		36 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:16103-366-11	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/22/2007	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/22/2007	

Labeler - Pharbest Pharmaceuticals, Inc. (557054835)

Registrant - Pharbest Pharmaceuticals, Inc. (557054835)

Establishment

Name	Address	ID/FEI	Business Operations
Pharbest Pharmaceuticals, Inc.		557054835	analysis(16103-366) , manufacture(16103-366) , pack(16103-366) , label(16103-366)

Revised: 12/2025

Pharbest Pharmaceuticals, Inc.